

RemarksApplication Status and Disposition of Claims

In the Final Office Action, the Office indicated that claims 1-34 are pending. Of those pending, claims 1-18 and 30-33 remain pending and under consideration, claims 19-24 and 34 having been withdrawn from consideration as directed to a non-elected invention.

Applicants note that the withdrawn claims are kept pending, subject to possible rejoinder.

The Action rejects claims 1-18 and 30-33.

Foreign Priority

The Office Action summary indicates that “some” of the certified copies of priority documents have been received. If the Office is missing any documents, Applicants respectfully request that the Office indicate what documents are missing so that they can be provided by Applicants.

Information Disclosure Statement

Applicants thank the Examiner for indicating consideration of the documents filed December 22, 2008.

Claim Rejections – Obviousness-Type Double Patenting

The Office Action maintains the rejection of claims 1-18 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 6, 12-17 of U.S. Patent No. 6,268,119 (hereinafter “SUMITA”) in view of Oka et al. (U.S. Patent No. 5,298,165, hereinafter “OKA 1”), Oka et al. (U.S. Patent Application Publication No. 2004/0251195, hereinafter “OKA 2”), Fukuda et al. (WO 02/087660, hereinafter “FUKUDA”), and Rubenstein et al. (Proc. Nat’l Acad. Sci. USA, 1995, 92:10119-10112, hereinafter “RUBENSTEIN”). Applicants respectfully disagree with the Office.

Initially, Applicants respectfully refer the Office to the prior arguments made in the prior response, all of which are maintained. In addition, Applicants present the following arguments with respect to the propriety of the rejection. In particular, Applicants submit that, as a fundamental issue, and putting all questions of obviousness aside, the rejection is simply improper under the circumstances.

Applicants respectfully note that an obviousness-type double patenting rejection is intended to prevent the Applicants (i.e., the assignee or a common inventor) from improperly extending the right to exclude under an earlier patent. Applicants note that MPEP 804 sets forth the policy behind obvious-type double patenting rejections:

The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent. The public policy behind this doctrine is that: The public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill in the art and prior art other than the invention claimed in the issued patent. *In re Zickendraht*, 319 F.2d 225, 232, 138 USPQ 22, 27 (CCPA 1963) (Rich, J., concurring). Double patenting results when the right to exclude granted by a first patent is unjustly extended by the grant of a later issued patent or patents. *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982).

(MPEP 804.)

As very clearly stated above, the issue is one of extension of rights in claims. That is, the policy seeks to prevent an unwarranted extension of patent rights. This is most often seen in a genus-species relationship, where an earlier genus claim is the basis for an obviousness-type double patenting rejection of a later species claim, or vice versa. There are other examples in which an obviousness-type double patenting rejection can properly be raised, but in every instance, there is an underlying public policy concern that rights in an earlier patent would be unfairly extended by the later application's claims.

Importantly, because the focus of an obviousness-type double patenting rejection is an unjust extension of the rights to exclude, the question is whether the later claims would be obvious in view of the earlier claims. As noted in MPEP 804,

When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992). This does not mean that one is precluded from all use of the patent disclosure.

The specification can be used as a dictionary to learn the meaning of a term in the patent claim. *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)("[W]ords in patent claims are given their ordinary meaning in the usage of the field of the invention, unless the text of the patent makes clear that a word was used with a special meaning."); *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250, 48 USPQ2d 1117, 1122 (Fed. Cir. 1998) ("Where there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meanings."). See also MPEP § 2111.01. Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970).

(MPEP 804.)

Applicants respectfully note that obviousness *per se*, which prevents a patent Applicant from obtaining a patent claim to an invention that would be obvious in view of the prior art, is addressed separately under 35 U.S.C. § 103. Applicants note that while the MPEP explains that the analysis is similar, the two prohibitions are separate, and they separately prevent different activities. Obviousness-type double patenting rejections seek to prevent the granting of claims that are obvious in view of prior claims, whereas 35 U.S.C. § 103 seeks to prevent the granting of claims that are obvious in view of prior disclosure. If an obviousness-type double patenting rejection could be made simply by combining the claims in one prior art patent with the disclosure of another patent, the distinction between the two prohibitions would be meaningless, and an obviousness-type double patenting rejection would be available to the Patent Office in practically every instance in which an Applicants' own prior art was the basis for a prior art rejection.

However, Applicants respectfully submit that this is exactly what the Office has done in this instance: take a prior art rejection under 35 U.S.C. § 103 and simply reuse it in an obviousness-type double patenting rejection. Applicants respectfully submit that

such practice by the Office is not supported by the MPEP, the Rules, Statutes, or any relevant case law.

To highlight Applicants' point, Applicants present pending claim 1 and the prior art claims in the table below.

SUMITA Claims	Pending Claims
<p>1. A cell separation method comprising the steps of:</p> <p>(a) introducing a cell-containing fluid, containing cells to be recovered and cells to be removed, into a cell-capturing means which substantially captures said cells to be recovered and substantially permits passage therethrough of said cells to be removed, whereby said cell-capturing means comprises one of a porous structure of nonwoven fabric having a fiber diameter of 1.0-30 μm and a porous spongy structure having a pore size of 2.0-25 μm;</p> <p>(b) taking out the resulting fluid containing the cells to be removed from said cell-capturing means; and</p> <p>(c) introducing a liquid with a viscosity of not more than 100 mPa·s and not less than 5 mPa·s into said cell-capturing means at a linear speed of at least 0.5 cm/min to recover therefrom said cells to be recovered which have been captured by said cell-capturing means.</p>	<p>1. (Original) A method for preparing a cell concentrate, which comprises:</p> <p>introducing a cell-containing solution that contains nucleated cells and unnecessary cells into a filter device comprising a filter material for substantially capturing the nucleated cells and for substantially giving passage to the unnecessary cells, so as to capture the nucleated cells by the above-described filter material and to discharge the unnecessary cells from the above device; and introducing a recovery solution into the above-described filter device, so as to recover the nucleated cells captured by the above-described filter material,</p> <p>wherein the above-described method is characterized in that the cell-containing solution that contains nucleated cells and unnecessary cells are separated into a layer that is rich in nucleated cells and a layer that is rich in unnecessary cells, the layer rich in unnecessary cells is first introduced into the above-described filter device, and</p>

	<p>the layer rich in nucleated cells is then introduced therein, so as to discharge the unnecessary cells remaining in the above-described filter device while capturing the nucleated cells by the above-described filter material, and a recovery solution is then introduced into the above-described filter device, so as to recover the nucleated cells captured by the above-described filter material.</p>
<p>6. A cell separation method according to claim 1, wherein the cell-capturing means is obtained by packing said porous structure into a container having a liquid inlet and a liquid outlet.</p>	
<p>12. A method according to claim 1, wherein the direction of introduction of the liquid with a viscosity of not more than 500 mPa·s and not less than 5 mPa·s is opposite to the direction of introduction of the cell-containing fluid containing cells to be recovered and cells to be removed.</p>	
<p>13. A cell separation method according to claim 1, wherein the cells to be recovered are nucleated cells.</p>	
<p>14. A cell separation method according to claim 13, wherein the nucleated cells are a mononuclear cell fraction containing hematopoietic stem cells.</p>	

15. A cell separation method according to claim 13, wherein the nucleated cells are hematopoietic stem cells.	
16. A cell separation method according to claim 1, wherein the cells to be removed are cells having no nucleus.	
17. A cell separation method according to claim 16, wherein the cells having no nucleus are at least one of erythrocytes and platelets.	

Of the claims included in this rejection, Applicants have only shown claim 1, because it is the most relevant to these arguments. Applicants have highlighted the features of claim 1 that are not disclosed or claimed in the primary reference, SUMITA. For these missing features, the Office is forced to turn to the secondary references. To be quite clear, SUMITA makes no reference at all to the claimed pre-treatment, and certainly does not claim such pre-treatment, and thus, the Office must find the disclosure of such pre-treatment in other documents.

Applicants respectfully submit that the Office's obviousness-type double patenting rejection is improper. There is no basis in the MPEP, the Rules, Statutes, or any relevant case law for combining art in this manner to support an obviousness-type double patenting rejection.

Still further, Applicants respectfully request that if the Examiner chooses to maintain this rejection, that she specifically explain how Applicants' claims constitute an unjust extension of the claims of SUMITA. That is, focusing on the public policy "that upon the expiration of the patent [the public] will be free to use not only the invention claimed in the patent but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill in the art and prior art other than the invention claimed in the issued patent," Applicants request that the Examiner explain, at least, how the bolded features recited in claim 1 above constitute any extension of *SUMITA's rights to exclude*.

In view of the foregoing remarks and the remarks made in the prior response, Applicants respectfully submit that the obviousness-type double patenting rejection is improper and should be withdrawn.

Claim Rejections – 35 U.S.C. § 103

The Office Action maintains the rejection of claims 1-17 and 30-33 under 35 U.S.C. § 103(a) as being obvious over SUMITA in view of OKA 1, OKA 2, FUKUDA, and RUBENSTEIN. The Office Action also rejects claims 1-18 and 30-33 under 35 U.S.C. § 103(a) as being obvious over SUMITA in view of OKA 1, OKA 2, FUKUDA, RUBENSTEIN, and further in view of Tanaka et al. (U.S. Patent No. 6,048,464, hereinafter "TANAKA").

Applicants respectfully disagree with the basis for the rejections.

In the Office Action, the Office rejects claim 1 over SUMITA and OKA 1 in view of OKA 2 and FUKUDA. The Action admits that SUMITA and OKA 1 do not teach using centrifugation to separate the cell-containing solution into a layer rich in nucleated cells, a nucleated-cell diluted layer, and a layer rich in unnecessary cells before introducing it into the filter device or adding HES before centrifuging the cell-containing solution. (Office Action, page 10, lines 10-14.) For these missing features, the Action relies on OKA 2 and FUKUDA, which the Office asserts teach centrifuging followed by introduction of the separated elements into nucleated cell-capturing filters. (Page 10, lines 15-20.) The Action asserts that such centrifugation would necessarily result in a cell gradient comprising a buffy coat at the top (layer rich in nucleated cells), plasma in the middle (nucleated cell-diluted layer), and an erythrocyte pellet at the bottom (layer rich in unnecessary cells). The Action asserts that OKA 2 and FUKUDA then introduce into the respective filters the separated components in the order of erythrocyte pellet first, plasma second, and buffy coat third. (Office Action, page 11, lines 1-3.)

Applicants respectfully note that the present invention recites, "the layer rich in unnecessary cells is first introduced into the above-described filter device, and the layer rich in nucleated cells is then introduced therein, so as to discharge the unnecessary cells remaining in the above-described filter device while capturing the nucleated cells by the above-described filter

material, and a recovery solution is then introduced into the above-described filter device.” According to the Office Action, OKA 2 and FUKUDA teach the introduction of a layer rich in unnecessary cells first (pellet), then the recovery solution (plasma), then the layer rich in nucleated cells (buffy coat). Applicants respectfully submit that this order reverses the order of the last two elements in Applicants’ claims, and thus, does not teach or suggest these elements. Applicants respectfully note that this point is particularly true with respect to claim 9, as the Office Action specifically states that SUMITA teaches that plasma can be used as the recovery solution. (Office Action, page 12, lines 8-12.)

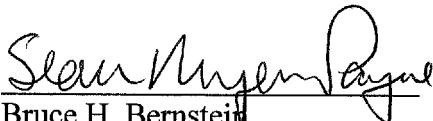
However, if it is the Office’s position that the plasma of OKA 2 and FUKUDA is not the recovery solution, and that some additional recovery solution would be used, then Applicants respectfully request that the Office point to such disclosure, or explain why such additional step would be obvious. Still further, in the event that the Office believes that an additional recovery solution would be used, Applicants respectfully request that the Office explain how claim 9 would be obvious – as the two positions would appear to be inconsistent.

Even assuming *arguendo* that the cited documents teach the *order* of introduction of unnecessary cells first, nucleated cells second, and plasma third, one of skill in the art would not have turned to OKA 2 or FUKUDA at least because FUKUDA teaches blood fractions containing 1) erythrocytes, granulocytes, and monocytes, 2) lymphocytes, and 3) platelets and plasma (page 4, [0063]). Furthermore, OKA 2 teaches the removal of white blood cells, not their collection.

In view of the foregoing remarks, Applicants respectfully request withdrawal of the obviousness rejections.

Applicants hereby authorize the charging of any required fees necessary for consideration of this paper to Deposit Account No. 19-0089. Any comments or questions concerning this application can be directed to the undersigned at the telephone number given below.

Respectfully submitted,
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